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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/019,680 | 01/04/2002 | James R. Ellsworth | 70869-0074US | 1027 |
| 7590 | 10/08/2004 | | EXAMINER | |
| Conrad J Clark Clark & Brody 1750 K Street N W Suite 600 Washington, DC 20006 | | | SORKIN, DAVID L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1723 | |

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/019,680 | ELLSWORTH ET AL. | |
| | Examiner | Art Unit | |
| | David L. Sorkin | 1723 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 August 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 7, "said portion" is recited. It is unclear which of the three previously mentioned portions is "said portion", the "peripheral portion" recited in line 5, the "portion extending across" recited in line 6, or the "portion of said cavity" recited in line 7.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. While the scopes of the claims are unclear, as discussed above, the claims have been considered with regard to the prior art to the extent possible.
5. Claims 1, 2, 4, and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin (US 4,001,122). Griffin ('122) discloses, in combination, a tube (10) comprising an inner wall forming a cavity adapted to contain a fluid to be subjected to centrifugation and a separator disk (12) in said tube adapted to separate components of said fluid having different specific gravities, said disk being made of a material having a

specific gravity near the specific gravity of red blood cells (see col. 2, lines 33-36 and col. 3 lines 3-5 where a density of 1.04 is disclosed, noting that the instant specification states on page 4 that 1.04 is the preferred density value is 1.04; the range 1.04-1.07 is also disclosed by Griffin); and comprising a peripheral portion adjacent and inner wall of said tube (see outer periphery of 12 in drawings) and a portion extending across at least a portion of said cavity (see drawings), said portion having an upper surface (for example the central, vertically oriented surface as shown in Fig. 4; which would be horizontal in the orientation of Fig. 1). The combination would be capable of being operated such that this surface, after centrifugation of blood, lies just below an interface with separated red blood cells, based upon the disclosed specific gravity of the disk and the specific gravities red blood cell component (about 1.09, although somewhat variable) and plasma (about 1.027). Smith (US 4,844,818) is cited as providing information concerning the specific gravity of blood components. See particularly cols. 1 and 3. Also, "where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on" *In re Fitzgerald* 205 USPQ 594 (CCPA 1980). See col. 2, lines 65-66 concerning the gap between the disk and tube. This gap would permit at least some degree of rotation. See the drawings regarding the shape of the disk.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 4,001,122). The combination of Griffin ('122) was discussed above. The relative dimensions of claim 6 are not disclosed. However, as held in *Gardner v. TEC Systems, Inc.* 220 USPQ 777 (Fed. Cir. 1984), if the only difference the prior art and the claims is a recitation of relative dimensions, the claimed device is not patentably distinct from the prior art unless a device having the claimed dimensions would perform differently.

Allowable Subject Matter

8. Claims 3 and 5 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/019,680
Art Unit: 1723

Page 6


David L. Sorkin
Primary Examiner
Art Unit 1723

David Sorkin